

REMARKS

In the Office Action mailed December 4, 2009, the Examiner rejected claims 11 and 21-34. By way of the foregoing amendments and the markings to show changes Applicants have amended claims 11, 34, and 35 and added new claims 36-39. The foregoing amendments are taken in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicant would otherwise be entitled in view of the prior art.

Further, by the present amendment, it does not follow that the amended claims have become so perfect in their description that no one could devise an equivalent. After amendment, as before, limitations in the ability to describe the present invention in language in the patent claims naturally prevent the Applicants from capturing every nuance of the invention or describing with complete precision the range of its novelty or every possible equivalent. See, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 62 USPQ2d 1705 (2002). Accordingly, the foregoing amendments are made specifically in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicants would otherwise be entitled.

New Claims and Amended Claims

Applicants amended claims 11, 34, and 35; no new matter has been added. Support for the amendment to claim 11 under 35 U.S.C. § 112 can be found in Figure 1 and Paragraphs 0019 and 0043 of U.S. Patent Application Publication No 2005/0008673. Support for new claims 36-39 can be found in paragraph 0046 and 0047.

35 U.S.C. § 103 Rejection

The office action allegedly rejected claims 11, 21, 24-26, and 32-34 as being unpatentable over Smedley (7,163,543) combined with Peyman (7,354,457). The office action further rejected claim 22, 27, and 28 over Smedley and Peyman and further in view of Bardenstein (4,743,255). The office action rejected claims 23 and 29-31 under Smedley and Peyman and further in view of Wong (6,692,759). Applicants traverse all of these rejections for the reasons set forth below.

a) Lack of Fact Findings

The office action has failed to present facts showing where each and every element of claim 11 is taught. Specifically, the office action has failed to show where the references of record

teach, “a solid walled plastic lumen having a lumen section that extends into the eye and wraps generally circularly around the cornea.” The office action failed to show where “the sustained release medium comprises a solid material,” “a sustained release medium including caprolactone and an antimicrobial within the interior of the lumen,” and “wherein the lumen has a circular cross section fixed inner and outer dimension” is taught. The office action has failed to present facts as to where every element of claim 11 is taught in a reference of record; therefore, applicants believe that a proper prima facie obviousness rejection has not been presented. Applicants respectfully request that the rejections be withdrawn for claim 11 and its dependents.

The office action has failed to show where the references of record teach the elements of claims 21 and 26. Specifically, the office action has failed to show where “the lumen has open ends” is taught. Thus, a proper prima facie rejection of claims 21 and 26 and their dependents 24, 28, 30, 33, and 34 has not been presented. Applicants respectfully request that the rejection be withdrawn.

b) Lack of Evidentiary Support for Fact Findings

The office action has not presented enough facts to support a prima facie obviousness rejection; moreover, the facts presented by the office action are not supported by the evidence. For example, the office action rejected claim 11 stating, “The stent has lumen that can be circular, and has plurality of side openings (col. 8, lines 1-3, 12-20; figure 3).” In turning to figure 3 first, Applicants do not see a circular lumen. Applicants then looked at col. 8 lines 1-3, which states, “have a plurality of side openings **77**, each of which is in fluid communication with the lumen **7**, for transmission of aqueous. The middle section **4** is connected to or coextensive,” and lines 12-20, which state, “Referring in particular to FIG. 3, as will be apparent to a person skilled in the art, the lumen **7** and the remaining body of the outlet section **9** may have a cross-sectional shape that is oval, circular, or other appropriate shape. The cross-sectional shapes of the lumen **7** and the outlet section **9** preferably conform to the shape of the outflow pathway into which the outlet section **9** is placed.” Applicants do not believe that any of these passages claim 11, which states, “lumen section that extends into the eye and wraps generally circularly around the cornea.” Thus, Applicants believe that the evidence provided in the office action does not support the assertion that Smedley teaches “wraps generally circularly around the cornea.”

The office action allegedly presented facts to show that Smedley teaches the limitations of claims 24 and 32-34; however, the office action never states what reference contains these facts or where these facts are contained in a reference. Specifically, the office action states, "The coating is expected to cover the openings as required by claims 24, 32-34. The teaching of the reference that 'the therapeutic agent can be loaded in interior location of the stent', would have suggested inner surface of the lumen of the stent or within the wall." Applicants have searched both Peyman and Smedley for the location of the material quoted by the office action; however, Applications were unable to locate this language in either reference. Applicants invite the examiner to show where the either Peyman or Smedley contain the quoted language; however, Applicants believe that as stands the facts presented by the office action are not supported by evidence. Moreover, the office action states that "[t]he coating is expected to cover the openings as required by claims 24, 32-34," but the office action has failed to show where the references teach covering the openings as indicated by the use of "expected" in the rejection. Thus, a prima facie rejection of claims 24 and 32-34 has not been presented.

c) Improper Application of KSR

Foremost, as has been previously pointed out, the office action has failed to present factual and/or evidentiary support for all of the rejections. Moreover, the office action has not presented evidence that all of the claims are obvious in view of the references of record and that the references are combinable. For example, claim 31 depends from claim 27. Claim 27 was rejected by the combination of Smedley and Peyman in view of Bardenstein. The office action failed to present any evidence showing that Wong is combinable with Smedley, Peyman, and Bardenstein (these three were used to reject claim 27). The office action simply states that Wong allegedly teaches the elements of claim 31 without presenting any evidence that Wong is combinable with Smedley and Peyman. Furthermore, the office action completely ignores additionally combining Wong with Bardenstein. Applicants do not believe that these four references are combinable.

Moreover, claim 35 depends from claim 31. Again the office action has failed to present facts and evidence that every element of claim 35 is taught by the references of record and that the references of record are combinable.

Under *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007) in light of *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), Applicants believe that a

proper 35 U.S.C. § 103 rejection was not made. Although the teaching-suggestion-motivation (TSM) test requirements as applied in *KSR* have been altered to be applied in a less rigid manner, the references still are not combinable. The Court in *KSR* said:

Often, it will be necessary...to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**.

KSR, 82 USPQ2d at 1395 (emphasis added). Even under *KSR* where the TSM test is applied less rigidly: (1) these four cited references are in dispute with each other, (2) there is no TSM to combine them, (3) there was no apparent reason to combine the elements, and (4) no explicit analysis was made. Moreover, the office action has not shown where any of these references teach: having a lumen section that extends into the eye and wraps generally circularly around the cornea, a solid walled plastic lumen, and a lumen has open ends. For example, Applicants do not believe it would be obvious for one skilled in the art to combine Smedley and Peyman with Bardenstien. Simply stated, Smedley teaches a treatment for ocular diseases (see title of the patent); whereas, Bardenstein "is directed to an improved intra-ocular device which can be readily located in the eye even after a subsequent (post-operative) condition or injury to the eye." (Abstract) Moreover, Bardenstein is directed to an "intra-ocular lens"—not "an implantable elongated hollow glaucoma drainage tube." Smedley in its detailed discussion clearly distinguishes between the two devices (see discussion of Figs. 4-8 and 12-15); thus, if Smedley intended to look to the teachings of an "intra-ocular lens" (of which Smedley was clearly aware of) Smedley would have done so. Since Smedley does not incorporate the teachings of an "intra-ocular lens" into its present invention, Applicants do not believe that Smedley and Bardenstein are combinable. The office action has failed to clearly show any teaching, suggestion, or motivation that Smedley and Peyman are combinable with Bardenstein; thus, Applications believe that a proper prima facie obviousness rejection has not been presented. Applicants respectfully request that the rejections be withdrawn and the claims allowed.

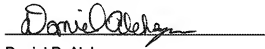
CONCLUSIONS

In view of Applicants' amendments and remarks, the Examiner's rejections are believed to be rendered moot. Accordingly, Applicants submit that the present application is in condition for allowance and requests that the Examiner pass the case to issue at the earliest convenience. Should the Examiner have any question or wish to further discuss this application, Applicant requests that the Examiner contact the undersigned at (248) 292-2920.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge our Deposit Account No. 50-1097 for any fee which may be due.

Respectfully submitted,

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